

CODEX COMMITTEE ON GENERAL PRINCIPLES

Twentieth Session, Paris, 3-7 May 2004

DEFINITION OF TRACEABILITY/PRODUCT TRACING

BACKGROUND :

1. The 49th (Extraordinary) Session of the Executive Committee (October 2001) discussed how to address the general issue of traceability/product tracing in the framework of Codex. The Executive Committee recommended that the Committee on General Principles consider the following aspects of traceability: as a food safety objective (i.e., as an SPS measure); and as a legitimate objective as a TBT measure. However, the Executive Committee was of the opinion that the first consideration should be given to the use of traceability/product tracing as a risk management option in the Working Principles for Risk Analysis and also noted the role of Committee on Food Import and Export Inspection and Certification Systems. The Executive Committee agreed that the Committees concerned (including the Committees on General Principles, Food Import and Export Inspection and Certification Systems, Food Hygiene and Labelling) should undertake work as they deemed appropriate, within their respective mandates¹.
2. The 50th Session of the Executive Committee (June 2002) agreed to add the term "product tracing after the word "traceability" as it was consistent with the terms under consideration in other Codex Committees. The Executive Committee agreed to retain both aspects without mentioning priorities and to indicate that first consideration should be given to the use of traceability/product tracing as a food safety risk management option, as already agreed at its 49th Session.
3. At its sixteenth session (April 2001), the Codex Committee on General Principles discussed traceability. All Delegations that spoke on this occasion, highlighted the importance of the issue and the importance of a uniform approach to the concept and application of traceability. Individual issues that Delegations and observers believed to be important in the development of the topic included: the place of traceability/product tracing in risk management; the use of traceability/product tracing for product integrity, authenticity and identification; the use of equivalent measures; practicability of traceability, and in particular the feasibility of its application in developing countries; consumer confidence and information concerning the nature and origin of products; the possibility of using traceability/product tracing for liability and redress.
4. The 17th Session of the Committee on General Principles (April 2001) discussed the need to undertake work on traceability/product tracing in the light of the recommendations of the Executive Committee. The Committee discussed in particular whether it should be considered in the framework of risk management as a matter of priority or whether it should be used for other purposes, such as the authenticity of consumer information. The Committee agreed that the Secretariat should prepare a discussion paper for further consideration of this issue at its next session. During the discussion, it was agreed that the results of the discussions in Regional Coordinating Committees would be integrated in the document prepared for consideration by the Committee².
5. The 18th Session of the Committee on General Principles (April 2003) resumed its discussion on "traceability/product tracing", on the basis of a paper prepared by the secretariat to report the views expressed during

¹ ALINORM 03/3, paras. 29-33

² ALINORM 03/33, paras. 5-13

the sessions of the Regional coordinating Committees³. The Committee concluded that there was sufficient support only to proceed with the development of a definition of "traceability/product tracing" for Codex purposes and agreed to establish an open-ended electronic working group under the direction of the Delegation of France to develop a draft for the consideration of the next regular session of the Committee.

6. During its third session (March 2002), the Task Force on Foods Derived from Biotechnology noted that the Executive Committee discussed traceability/product tracing as a general issue confronting Codex. The Task force recalled that the Secretariat paper⁴ prepared for the Commission (July 2001) had pointed out that traceability/product tracing was not new to Codex but that it had not been treated in a systematic manner and that any measures requiring traceability/product tracing must be justified as having a food safety objective (i.e., as an SPS measure), or having a legitimate objective as a TBT measure. The Task force noted that the Executive Committee had generally supported the analysis and approach outlined in the Secretariat paper. In the context of its discussion on the Draft Principles for the Risk Analysis of foods derived from modern biotechnology at step 7, the Task Force agreed that the resolution of this issue was important in order to reach a final conclusion on the text of the Draft Principles. It amended the Draft principles to place the question of traceability/product tracing into context as one of the tools for implementation and enforcement of risk management measures, without prejudice to its use for other purposes.

7. During its fourth session (March 2003), the Task force had an open discussion on traceability. In his summary, the Chairperson outlined the main elements of the discussion : consideration of traceability/product tracing had started in this Task Force and there was consensus to continue further discussion in the framework of Codex; traceability/product tracing was an important element to ensure food safety throughout the food chain; it could address the request of consumers for transparency and improved information; and its implications for developing countries should be further considered, especially to ensure fair trade.

8. At its tenth session (February 2002), the Codex Committee on Food Import and export Inspection and Certification Systems (CCFICS) addressed the issue of traceability/product tracing in the context of food inspection and certification systems. The Committee noted that the concept of "traceability" was already included in many Codex texts and was linked in most cases to product identification and recall procedures, that Codex texts generally did not apply traceability/product tracing to the origin of foods and ingredients although Country of Origin provisions included traceability/product tracing requirements in at least two Codex texts, that traceability/product tracing might also be used to ensure fair practices as it correlated to the prevention of deceptive practices (e.g., organically produced food) as a legitimate objective described by the WTO Agreement on Technical Barriers to Trade. The Australian Secretariat's paper⁵, tabled at this meeting, described traceability/product tracing as a means to preserve the identity of the food product and according to several definitions adopted by the Commission, the concept of traceability/product tracing might be considered to be included as a requirement. The Committee considered different scenarios to address traceability/product tracing in the context of its mandate such as to acknowledge the fact that inspection and certification may be in some situations be the most efficacious means of implementing a requirement for food to be traceable; to attempt to codify the circumstances in which traceability/product tracing should be applied as a requirement. The Committee decided that a working group led by Switzerland, should draft a discussion paper for circulation, comment and further consideration at its next meeting.

9. At its eleventh session (December 2002), the CCFICS considered the elements, identified by the Working Group, convened by Switzerland (Fribourg, August 2002), related to traceability/product tracing : the ability to identify a food (product identification), how it was changed (if appropriate), where it came from and where it was

³ CX/GP 03/7

⁴ ALINORM 01/21, Part IV- Add.1

⁵ CX/FICS 02/INF.2

sent (one step backward and one step forward) (product information) and the linkages between product identification and product information, while also noting that the applicability of these elements would depend on the objectives being pursued by the individual texts. The Committee agreed that responsibility for the development of a definition for traceability/product tracing rested with the CCGP; that CCFICS was responsible for traceability/product tracing related to food inspection and certification systems, and that existing Codex texts related to food inspection and certification as well as discussions in CCFICS and other Codex Committees and written comments submitted should be taken into account in the determination of the current adequacy and applicability of CCFICS texts related to traceability/product tracing and the need for further work in this area. The Committee reconvened the Working Group on Traceability under the Chairmanship of Switzerland in order to carry out the above review and to complete its mandate. The Working Group should take into account discussions on traceability/product tracing in other relevant Codex committees.

10. At its forty-fourth session (October 2001), the Codex Committee on Food Hygiene recalled the recommendation of the 49th Session of the Executive Committee which agreed that it should be for the Committees concerned (including the Codex Committees on General Principles, Food Import and Export Inspection and Certification Systems, Food Hygiene and Food Labelling) to undertake work on traceability/product tracing as they deemed appropriate, within their respective mandates. In this regard, the CCFH noted its previous decision that traceability/product tracing would be considered in the context of its work on the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management and was of the opinion that specific work on traceability/product tracing as related to food hygiene was premature. At its forty-fifth session (January 2003), the Committee noted, in the same context, that ongoing discussions within other Codex committees, including the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) and the Codex Committee on General Principles (CCGP), should be taken into account before proceeding further on the proposed definition for product tracing/traceability.

11. At this thirtieth session (May 2002), the Codex Committee on Food Labelling recalled the recommendations of the 49th Session of the Executive Committee concerning the consideration of traceability/product tracing in Codex and noted the work undertaken by other committees in this area and that several Codex labelling texts and commodity standards included provisions concerning product tracing, including country of origin. Some delegations and observers pointed out that traceability/product tracing was especially relevant to the work of the Committee in order to ensure the authenticity of labelling ; a more systematic approach was necessary and principles should be defined to ensure consistency in the approach to labelling issues. The work of the Committee on Food Import and Export Inspection and Certification Systems would not address specific labelling issues. They also stressed the importance of the input from the Committee on Food Labelling to facilitate the general debate in the Committee of General Principles. Other delegations and observers expressed the view that it was premature to undertake specific work on traceability/product tracing since the CCGP was expected to provide general guidance for Codex committees and the CCFICS was already working in this area. It was also noted that no definition of traceability/product tracing had been developed for the purposes of Codex work, and that this question should be addressed first by the CCGP. There was no consensus on the need to undertake specific work on traceability/product tracing and food labelling but the Committee agreed that this question should be discussed further at the next session, taking into account the work undertaken by other Committees. The Thirty-first session (May 2003) essentially repeated the same point.

PARTICIPATION AT THE OPEN-ENDED ELECTRONIC WORKING GROUP :

12. The 18th Session of the Committee on General Principles (April 2003) established an open-ended electronic working group under the direction of the Delegation of France to develop a draft for the consideration of the next regular session of the Committee.

13. At various stages in the development of this paper, suggestions and comments have been received from

Finland, New Zealand, ..., the observer from the European Commission, ALA (Asociación Latinoamericana de Avicultura), EAN International,...

GENERAL ISSUES ON TERMINOLOGY AND DEFINITIONS :

14. In its 2003 paper⁶, the Codex secretariat identified two components in the concept of traceability/product tracing : the ability to trace products and the act itself, the success of which relies on the existence of an information system.

15. At its first meeting in Fribourg (August 2002), the working group on traceability/product tracing, in order to fulfill its mandate, had to agree on an interim definition of traceability/product tracing (a "working definition"). The relevance of this achievement was recognized by several Regional Coordinating Committees. In this regard, the Working Group considered the following possible elements: the ability to identify a food (product identification), how it was changed (if appropriate), where it came from and where it was sent (one step backward and one step forward) (product information) and the linkages between product identification and product information.

16. In its 2003 paper⁷, the Codex secretariat noted that the appropriateness of the ISO 9000:2000 definition of "Traceability"⁸ for Codex purposes has been questioned. The ISO definition, being very broad, encompasses the concepts in the Secretariat's paper on "traceability/product tracing" discussed by the 49th Session of the Executive Committee ; it is possible, however,⁹ that the definition is too broad for Codex purposes. The Codex secretariat suggested the development of an operational definition that would be consistent with the ISO definition, but would be narrower and confined to Codex purposes. This idea received a general support from the Committee at its 18th session : Many delegations noted that the general ISO definition was not appropriate for Codex purposes and that the same terminology was used to describe very different systems..

17. Guidelines or principles relating to "traceability/product tracing" would more than likely relate to both aspects (food safety and matters other than food safety) regardless of efforts to theoretically separate the two concepts. Once there is the ability to trace a product, that product can be traced for whatever purpose. The question arises as to the degree of detail required in the record keeping at each step in the production, processing and marketing chain. "Traceability/product tracing" has the benefit, however, of being applicable to the management of previously unforeseen or unidentified risks.

18. The 50th Session of the Executive Committee (June 2002) agreed to add the term "product tracing" after the word "traceability", as it was consistent with the terms under consideration in other Codex Committees. During its session held prior to the 18th session of the Codex Committee on General Principles, one Regional Coordinating Committee welcomed this addition, since, in its view, this new term would be the appropriate terminology to employ for the concept of the tracing of food products and/or their ingredients . However, other comments emphasised that the terminology surrounding traceability/product tracing was unclear, that this would be a substantial obstacle to achieving consensus and that, moreover, there were substantial problems in understanding

⁶ CX/GP 03/7

⁷ CX/GP 03/7

⁸ *Traceability: ability to trace the history, application or location of that which is under consideration.* NOTE 1 When considering product (3.4.2), traceability can relate to — the origin of materials and parts, — the processing history, and — the distribution and location of the product after delivery. NOTE 2 In the field of metrology the definition in VIM:1993,6.10, is the accepted definition (i.e In metrology and laboratory accreditation systems, the term traceability means a process whereby the indication of a measuring instrument (or a material measure) can be compared with a national standard for the measurand in question in one or more stages (International Laboratory Accreditation Conference: ILAC-G2: 1994 Traceability). The ISO definition also refers to this aspect of traceability. This aspect of traceability falls within the terms of reference of the Codex Committee on Methods of Analysis and Sampling, but for the purposes of this paper it will not be discussed further. -- cf. ALINORM 01/21 Part IV - Add. 1 footnote 2).

⁹ ALINORM 01/21 Part IV - add. 1

the meaning of the term traceability/product tracing in different languages. There was some suggestion that one should not open a semantic discussion, at this stage, and that it would be preferable to reach an agreement on a definition of the system, whatever terminology is used, and on how it should be implemented.

RECOMMENDATIONS TO THE CODEX COMMITTEE ON GENERAL PRINCIPLES :

19. The Committee is invited :

- To discuss the proposed draft definition in Appendix 1 and advance the text in the step procedure.
- To decide on the best way to address the others concerns expressed in the written comments and during the discussion (cf. Appendix 2).

PROPOSED DRAFT

DEFINITION OF "TRACEABILITY/PRODUCT TRACING"

FRENCH

"La mise en œuvre des moyens d'assurer, à n'importe quel stade de la chaîne alimentaire, que le cheminement d'une denrée alimentaire et les informations pertinentes la concernant (au regard de sa sécurité sanitaire et/ou des pratiques loyales dans son commerce) sont connus, notamment :

- identification du produit,
- information sur le produit :
 - l'historique de sa transformation (le cas échéant),
 - son origine et sa destination (une étape en amont et une étape en aval), ainsi que
- la mise en relation de l'identification du produit et des renseignements sur le produit.

Ces informations sont enregistrées par chaque opérateur concerné et sont conservées sous une forme bien organisée et facilement accessible."

ENGLISH

"The implementation of measures to ensure, at any stage of the food chain, that the movement of a food and the relevant informations about it (pertaining to food safety and/or fair practices in its trade) are known, including :

- product identification,
- product information :
 - how it was changed (if appropriate),
 - where it came from and where it was sent (one step backward and one step forward) and
- the linkages between product identification and product information.

These informations are recorded by each business involved and are stored in a well organised and readily accessible format."

SPANISH

La puesta en marcha de las medidas destinadas a asegurar que el recorrido de un producto alimentario, en cualquier eslabon de la cadena alimentaria, y las informaciones pertinentes que se refieren a este (en cuanto a su seguridad sanitaria y/o a las practicas leales en su comercio), estan conocidos, en particular :

- identificación del producto,
- información sobre el producto :
 - la manera en que se había transformado el mismo (de corresponder)
 - el origen y lugar de destino del mismo (una etapa hacia atrás y una hacia adelante); y
- los vínculos entre la identificación del producto y la información sobre el producto.

Estas informaciones estan registradas por cada operador involucrado y estan guardadas bajo una forma bien organizada y de facil acceso.

OTHER RELEVANT TOPICS

ABOUT TRACEABILITY/PRODUCT TRACING

TRACEABILITY IN THE FRAMEWORK OF CODEX :

20. In its paper (ALINORM 01/21 Part IV Add.1), the Codex secretariat clarified the place of traceability/product tracing in the framework of Codex, in relation to the Codex mandate and the issues to be addressed, in Codex standards and related texts, to accommodate provisions on traceability/product tracing. This paper also gave some thought on how to traceability/product tracing could be implemented.

21. According to ISO, traceability/product tracing can entail high costs. A decision to apply traceability/product tracing should therefore be justified and the justification documented. Consideration must be given to the reasons for applying traceability/product tracing for food products and the extent to which traceability/product tracing is to be required as part of a food standard, code of practice, food labelling text or similar document. Such reasons must lie within the overall mandate of the Commission, namely: *To protect the health of consumers and ensure fair practices in the food trade.*

22. The ISO definition of “Traceability” states in a note that “*All aspects of traceability requirements, if any, should be clearly specified, for example, in terms of period of time, point of origin or identification*”. The ISO definition implies that traceability/product tracing may or may not be required, or may begin at a certain point within the production chain, or may end at a point before the end of the chain.

23. The extent to which traceability/product tracing may be applied “*to protect the health of consumers*” may be considered as part of a food safety risk management decision. Such a decision would also need to take into account other measures that would achieve the same ALOP that may be less costly or may be more appropriate in a given situation. Such decisions may need to be specified on a case-by-case basis taking into account: i) the nature of the risk; and ii) the ability to manage the risk by the use of traceability/product tracing or by other means.

24. The use of traceability/product tracing “*to ensure fair practices in the food trade*” correlates to the “*prevention of deceptive practices*” as a legitimate objective described by the WTO Agreement on Technical Barriers to Trade. A decision to apply traceability/product tracing would need therefore to specify whether it is to be applied throughout the production and distribution chain or only to some part of the chain, on a case-by-case basis taking into account: i) the legitimate objective being fulfilled; ii) the risks that non-fulfilment would create; and iii) whether or not the legitimate objective can be addressed in a less trade-restrictive manner.

25. Traceability/product tracing may also serve to meet the needs of contracting parties in fulfilling the requirements of Article 18 of the Cartagena Protocol on Biosafety in regard to living modified organisms that are intended for direct use as food or feed, or for processing and are not intended for intentional introduction into the environment.

26. There is the question of how traceability/product tracing is to be applied: what are the modalities to be applied, especially in regard to international food trade; what information needs to be transmitted from one regulatory authority to another, and when; how are the traceability/product tracing requirements of voluntary or mandatory food quality and safety management systems to be integrated into an international regulatory framework. Consideration should also be given to its practicability and in particular the feasibility of its application in

developing countries.

OTHER CONCERNS :

27. At several points, during past discussions, various concerns were expressed, the nature of which prevented them to be addressed in the proposed draft definition. These concerns can be grouped under the following headings :

PURPOSE

28. The importance in establishing a comprehensive traceability/product tracing system in order to trace-back and withdraw products from the market, which were susceptible in provoking harmful effects to the health of consumers, was stressed.

29. There is willingness to consider traceability/product tracing as a food safety risk management measure but The system should not be extended to non-food safety related areas such the verification of authenticity or for labelling purposes

30. The mandatory or regulatory use of traceability/product tracing for purposes other than food safety risk management to protect consumers' health, meets opposition..

31. such a system should not be extended to the regulation of commercial "Identity Preservation". The use of traceability/product tracing for these purposes was a commercial response to consumer demand and could therefore be left to market forces to determine when and how the system should be applied.

32. Traceability/product tracing was used as a voluntary measure to provide added value and premium prices in situations where particular claims were being made as to the nature of the food, such as "organic" foods to make such tracing systems mandatory would eliminate the comparative advantage enjoyed by the producers of such foods and they would be unable to recoup the additional costs involved in the maintenance of a traceability/product tracing system..

CONSISTENCY WITH WTO SPS AND TBT AGREEMENTS

33. The use of a system of traceability/product tracing should be consistent with the provisions of the WTO SPS and TBT Agreements and be not more trade-restrictive than necessary

ISSUES OF COST

34. The importance of addressing cost implications, and the possible denial of market access related to the implementation of traceability/product tracing, including the subsequent economic impact on production systems for developing countries, and especially the least-developed ones, was noted.

35. Traceability/product tracing could lead to economic benefits in certain circumstances and that the costs of the absence of traceability/product tracing should also be taken into account. In particular, the absence of traceability/product tracing systems in the production chain and food businesses might actually lead to a lack of control in food-borne disease outbreaks and/or the withdrawal of unsafe foods from the market in emergency situations.

36. The costs of such systems should be borne by all concerned, but that certification and auditing bodies could also underwrite these systems.

37. This system should only be used as a risk management option on a voluntary basis and that there should be a cost/benefit analysis before proceeding with the use of traceability/product tracing. If a cost/benefit analysis was to be carried out then the costs of not implementing the traceability/product tracing system should also be analyzed.

SITUATION OF DEVELOPING COUNTRIES

38. A system of traceability/product tracing that would serve multiple purposes would most likely be costly, especially for producers and small-scale enterprises in developing countries

39. Traceability/product tracing would be more difficult for developing countries to implement. Even “trace-back” was not practical for developing countries where most agricultural production was on small farms. Economic considerations should be taken into account and traceability/product tracing could only be considered as an optional tool for those industries that could afford to use it.

40. Traceability/product tracing should be applicable only to processed foods and exclude primary foods and processes

41. State-regulated systems of traceability/product tracing for the determination of product authenticity would benefit developing countries wishing to market and export “organic” foods. Such regulations were in force in some developed countries.

ALTERNATIVE SYSTEMS

42. The HACCP System required similar record-keeping and provided the tools necessary for food safety risk management. The Codex General Principles of Food Hygiene already contained the elements of record-keeping that were necessary to establish a traceability/product tracing system that would be applicable to all food products throughout the food chain.

GUIDELINES TO IDENTIFY SITUATIONS WHERE TRACEABILITY/PRODUCT TRACING IS THE METHOD OF CHOICE.

43. Traceability/product tracing was not capable in itself of ensuring product safety. Traceability/product tracing is not a stand-alone activity, i.e., it is a tool that may be applied within a broader food control system.

44. The need for and scope of application and specifications regarding each element of traceability/product tracing should be considered on a case-by-case basis according to the objective(s) of the food control system within which traceability/product tracing is implemented.

45. Decisions on whether a mandatory traceability/product tracing system should be implemented should be based on whether such an approach is necessary to achieve the objectives of the food control system.

46. Comprehensive application of traceability/product tracing would not serve the desired purposes and so it shall be applied strictly on a case-to-case basis.